

Institutional Review Board
North Dakota Department of Human Services
**Change in Procedure or Principal
Investigator Application**

Type all answers

Local Sites to be Notified: (Circle) WCHSC LRHSC BHSC SEHSC NWHSC State Hospital
 NEHSC SCHSC NCHSC NDDC Other:

Please check appropriate changes: (Attach a complete copy of all additions/revisions, changes highlighted.)

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Addendum
Amendment
Modification
Other: _____

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Revised protocol
Revised Informed Consent
New Title

1. General Information

Principal Investigator: _____ ☐ DHS ☐ Non-DHS
Address: _____
Dept./College: _____ Box No. _____ Tel./Fax #: _____
Co-Investigator(s): _____

2. Protocol Information

Title of Project: _____

Sponsor/Grant agency: _____

3. Amendment Information - Please Complete Entire Section

Describe the proposed additions/revisions in appropriate detail: *(Tab to indented next line)*

Describe any significant change in the risk/ benefits ratio for the participants from these additions/revisions:
(Tab to indent)

Have you revised the Informed Consent to include any of the additions/revisions?

☐

Yes

☐

No

If yes, please attach a copy of the revised consent form and **highlight** all revisions.

4. Addition of New Co-Investigators to Protocol

Your acknowledgment is requested to assure the North Dakota Department of Human Services' Institutional Review Board that you are aware of the existence and status of this research activity and that you agree to the statements made in the original IRB application including the "Statement of Assurance."

Co-Investigator-Print Name

Co-Investigator-Signature

Date

Co-Investigator-Print Name

Co-Investigator-Signature

Date

Co-Investigator-Print Name

Co-Investigator-Signature

Date

Co-Investigator-Print Name

Co-Investigator-Signature

Date

Co-Investigator-Print Name

Co-Investigator-Signature

Date

5. Principal Investigator Statement of Assurance

"I understand that I cannot initiate any changes in my approved protocol before I have received approval and/or complied with all contingencies made in connection with that approval."

Signature of Principal Investigator

Date

Please return this application and any attachments to:

Mental Health and Substance Abuse Services
Attn: DHS IRB Chair
1237 West Divide Ave, STE. 1C
Bismarck, ND 58501-1208

Change in Procedure or Principal Investigator

IRB Proposal # _____

FOR IRB USE ONLY:

_____ Full Board Review

_____ Exempt

_____ Expedited Category #

Expedited Review By:

IRB Chairperson Signature

Date